



APPLICATION REQUEST FOR A CHRONIC DIALYSIS CLINIC (END-STAGE RENAL DISEASE)



This letter is to assist you in preparing a chronic dialysis clinic licensing and/or certification (for Medi-Cal Title 19 and/or Medicare Title 18 reimbursement) application package to the California Department of Public Health (CDPH) Licensing and Certification (L&C) Program for:

- Initial application package for a chronic dialysis clinic; or
- Change of ownership (CHOW) application package for a chronic dialysis clinic.

A state license is required to operate a chronic dialysis clinic in California, which is defined as:

Chronic dialysis clinic means a “free-standing specialty clinic, which provides less than 24-hour care for the treatment of patients with End-Stage Renal Disease”.

An application is required for: (1) a new (initial) chronic dialysis clinic; and (2) whenever a CHOW occurs. A CHOW is the only “change” requiring a new application to be submitted to L&C. All other changes (besides a CHOW) must also be reported to L&C (in writing). These other changes do not require submittal of a new application package.

For your convenience, the [attached checklist](#) has instructions to complete the forms required for licensing and/or certification of a chronic dialysis clinic. The [checklist](#) provides specific item numbers that applicants typically have encountered problems in submitting incorrect or missing information. Please make sure that all item numbers in each form are completely filled out. For example: (1) the applicant’s formal name must be consistently the same throughout all the documents in the application package; or (2) in some instances, a specific attachment may need to be submitted with a specific form.

Please read each required application package form carefully and provide all requested supplemental documents. **DO NOT LEAVE ANY ITEMS BLANK. NOTE:** If a question does not apply, please respond with “Not Applicable” or “N.A.” **Do not make changes to these forms.** Do not use white out/correction fluid to make corrections. To correct an error, place a single line through the entry and enter the correct information. The individual responsible for making the correction must initial and date the correction. You should retain a photocopy of the completed documents for your files. We may need to contact you in the future and we will be referring to the information in the documents you provided.



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In addition, a check or money order, made payable to the “**California Department of Public Health**” for the licensing fee, determined pursuant to Section 1266 of the Health & Safety Code, must accompany the required forms before your application will be processed. The licensing fees change annually; therefore please check the current licensing fee for a chronic dialysis clinic which is posted on the L&C website at:

<http://www.cdph.ca.gov/pubsforms/forms/Pages/HealthFacilities.aspx>

The application fee will NOT be returned if the application is withdrawn or denied.

The application package review process will consider the licensee’s and board members’ prior compliance history of all facilities operated by those individuals in California and nationally. The applicant and associates must demonstrate substantial compliance with state and federal requirements for all facilities that they operate.

Failure to demonstrate substantial compliance historically may result in the denial of your application package. You will be notified in writing of L&C intent to deny the application.

All completed chronic dialysis clinic **application packages must be submitted to the local L&C district office who process chronic dialysis clinics (East Bay, Los Angeles, San Bernardino, San Diego North and Santa Rosa/Redwood Coast).**

The district office will review the application package for completion. A list of district offices and appropriate contacts are located on the L&C website at:

<http://www.cdph.ca.gov/certlic/facilities/Pages/LCDistrictOffices.aspx>

Please NOTE the following:

1. There are some differences between documents required for a CHOW and “initial” application packages that are noted on the [checklist](#).
2. An initial survey is part of the application process for “new” chronic dialysis clinic facility applications.
3. The initial survey is a scheduled survey conducted by L&C district offices in the facility.
4. If your agency wants to provide services to **Medicare beneficiaries** (under Title 18) or **Medi-Cal beneficiaries** (under Title 19) you will need an additional **certification survey** that is unannounced and conducted by one of our L&C district offices.



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5. Once you have had your initial licensing survey, you need to notify the L&C district office that you are ready and prepared to have an initial certification survey.
6. In addition, you must be in compliance with state licensing laws and federal conditions of participation.

The district office will notify you when the application has been approved and will schedule an initial licensing survey. NOTE: YOU MUST BE READY FOR THE INITIAL LICENSING SURVEY UPON NOTIFICATION. It is L&C's policy that, except in unusual circumstances, only one inspection visit will be made. Failure of the facility to be in substantial compliance, at the time of the visit, will result in the "denial" of the application package. Any further activity regarding your request, after such denial, will require a new application and license fee.

PLEASE NOTE: A license will not be issued until both the application is approved and, if required, a successful licensing survey is conducted.

If you have any questions, please contact your local district office administrator located on the district office L&C website listed above.

Sincerely,

ORIGINAL SIGNED BY:

Anna Ramirez, Chief
Field Operations Branch—Region IV



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Form Number	Item Number on Form	PROVIDER CHECKLIST for a CHRONIC DIALYSIS CLINIC (End-Stage Renal Disease)	Check List
		<p>The following is a quick reference of <u>SOME</u> of the questions found on the required forms. It includes the form number, name of form, and an explanation of <u>SPECIFIC</u> requirements and/or attachments needed for specific forms. This is <u>NOT</u> an all-inclusive list of the questions that need to be answered so read the questions and instructions on each form.</p>	
LICENSURE CHRONIC DIALYSIS CLINIC – End-Stage Renal Disease (ESRD) Includes the forms and information to be “licensed”			
HS 200	Licensure & Certification Application NOTE: Please read the instructions on the HS 200 form prior to completion of the form. Also, pay close attention to the following items:		
	A.11.	Construction. If this is a NEW facility, SUBMIT the following: <ul style="list-style-type: none"> Certification of compliance with CA Building Standards Code (OSHPD 3) Evidence of compliance with Title 24 Floor plan Zoning approval from city or county 	
	B.1.	Licensee’s name. The licensee’s formal organization name must be consistent throughout all documents.	
	B.2.	Nonprofit. SUBMIT a copy of Internal Revenue Service letter of determination status, if the chronic dialysis clinic is a nonprofit entity,	
	B.3.	Owner type. SUBMIT an organization chart/flow chart if the owner is a profit or nonprofit corporation, limited liability company (LLC), or general partnership. The organization chart needs to display the following: <ul style="list-style-type: none"> Applicant’s owners/officers All facilities the applicant is involved with Parent company of applicant, if applicable, and all of their facilities – see B.6. 	
	B.5.a.	Licensee’s “other” Facility Involvement. Answer all aspects of the question.	
	B.5.b.	Revocation, suspension, etc. action. If applicable to the licensee, SUBMIT the information requested.	
	B.6.	Subsidiary information. If there is a “subsidiary” (parent company) SUBMIT: <ul style="list-style-type: none"> An organization chart with the parent company name and tax ID number A listing of all owners/officers of the parent company A listing of all facilities the parent company is involved with 	



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	C.1.a.	Management Company. This question <u>does not</u> apply to chronic dialysis clinics.	N/A
	C.1.b.	“Interim” Management Company Agreement. <ul style="list-style-type: none"> • If there is an “interim” Management Company Agreement, between the current and the prospective licensee, SUBMIT a signed and dated copy of any Agreement. • The Agreement must state the current licensee still has responsibility for the facility. The interim management company agreement is also addressed under “Change of Ownership” (CHOW) requirements on page 7 of these instructions.	Also see CHOW on page 7 of this letter
	C.2.	Name of “proposed” and “current” facility. Enter both facility names if this is a CHOW.	
	C.6.a.	Administrator. SUBMIT the HS 215A form for the Administrator of the facility.	
	C.7.	Ownership. <ul style="list-style-type: none"> • List all persons having 5% or more ownership, unless “nonprofit”. • SUBMIT the HS 215A form for each of these persons. 	
	C.8. thru C.10.	Financial resources, over concentration, and Program Plan approval. These questions are “N/A” for an ESRD facility.	N/A
	D.1. & 2.	Property ownership. SUBMIT a copy of the Grant Deed, Bill of Sale, Lease, Sublease, or Rental Agreement between the owner of the property and the proposed licensee.	
	F.1.	Signature. “Original” signature is required and MUST be signed by the LICENSEE (not the Administrator).	
	Attach E-1	Management Company Information. Attachment E-1 <u>does not</u> apply to chronic dialysis clinics.	N/A



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HS 215A	Applicant Individual Information NOTE: Please read the instructions on the HS 215A form prior to completion of the form. This form must be completed for the following persons with ORIGINAL signatures:		
		<ul style="list-style-type: none"> Administrator of the facility Board members, directors, partners, and corporate officers of the applicant organization and parent organization. Each person having a beneficial interest of 5% or more in the applicant organization and parent organization. LLC managers and members Partners 	
	Signature	Signature. Original "signature" is required.	
	Facility Information Sheet	Facility Information Sheet. Each individual must complete and SUBMIT the "Facility Information Sheet" for each facility with which they have a <u>current</u> or <u>past</u> relationship (going back 3 years). The following <u>MUST</u> be completed for each facility: <ul style="list-style-type: none"> Facility name Address of facility Type of facility Type of business entity Person's <u>nature</u> of involvement Person's dates of involvement This Sheet must also include any facilities licensed by the California Department of Social Services.	
HS 309 1 st page	Administrative Organization		
	2.	Administrator of Corporation or LLC – This is usually the CEO/President.	
	3. thru 7.	Corporations need to SUBMIT : <ul style="list-style-type: none"> A copy of the Filing Statement from Secretary of State Copy of all Articles of Incorporation Copy of By-Laws 	
	9.	Governing Board of Directors. SUBMIT the HS 215A form for each person listed under this item.	
	10.	Board Officers. SUBMIT the HS 215A form for each person listed under this item.	



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HS 309 2 nd page	Organizational Structure		
	1.	California Out-of-State Corporations, LLC, etc. SUBMIT a copy of the Certificate of Qualification from the California Secretary of State.	
	3 thru 4.	Public Agency. SUBMIT a copy of the Resolution.	
	5.	Item 5. Corporations and Partnerships need to complete Item 5	
	Bottom of page	Partnerships need to SUBMIT: <ul style="list-style-type: none"> • A copy of the Partnership Agreement • Copy of the California Secretary of State filing 	
	Bottom of page	Limited Liability Companies (LLC) will need to SUBMIT: <ul style="list-style-type: none"> • Copy of Filing Statement from the Secretary of State • Copy of Articles of Organization • Copy of Operating Agreement • List of Members / Holders / Officers / Managers 	
HS 602	Transfer Agreement Between		
		The Transfer Agreement needs to be current. Please submit a copy of transfer agreement.	
DHCS 1051	Civil Rights Compliance Review		
		Send directly to Office of Civil Rights – address is on last page of the form.	
STD 850	Fire Safety Inspection – the district office will initiate this form		From DO
None	Business Plan Letter		
		SUBMIT a <u>business plan</u> letter explaining (with detailed information) your “Business Plan” for operation of the ESRD, including a description of all services to be provided.	
None	Change of Ownership		
		<ul style="list-style-type: none"> • SUBMIT all of the forms required for an “initial” application, listed above, plus the following: • Signed and dated copy of any “interim” Management Agreement. Refer to the HS 200 form, Item C.1.b. • A letter from the prospective licensee to CDPH stating where the stored patient medical records will be maintained, and that the records will be made available to the previous licensee. 	



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CERTIFICATION CHRONIC DIALYSIS CLINIC – End Stage Renal Disease (ESRD) Includes the forms and information to be “certified” with Medi-Cal and/or Medicare			
HS 269		Application for Medi-Cal Certification as a Primary Care Clinic Provider	
HS 328		Notice – Effective Date of Provider Agreement	
DHCS 9098		Medi-Cal Provider Agreement	
		Do not leave any questions blank. Enter N/A if not applicable. Signature page (page 9) must be notarized .	
CMS 855A		Medicare General Enrollment Health Care Provider/Supplier Application	
		This form is available from the Federal “Department of Health and Human Services”. The completed form should be mailed directly to the appropriate Fiscal Intermediary.	
CMS 3427		End-Stage Renal Disease Application/Notification and Survey and Certification Report	
		The applicant will need to complete and provide all information that they have on Sections 1 thru 24 (except #2). The surveyor will bring a copy of this form to the facility to update and add additional information, when the certification survey is conducted.	